REMARKS

Allowable Claims

Claims 12, 60, 65, 70 and 71 were indicated in the previous Office Action as being allowable if rewritten in independent form. In response to the previous Office Action, the Applicant rewrote each of claims 12, 60, 65, 70 and 71 in independent form. However, the previous indication of allowability has been withdrawn.

Claim Rejections – 35 USC § 103

Claims 1, 2, 5-15, 17, 18, 20, 35-37, 52, 54, 56 and 59-75 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,669,909 to Zdeblick et al. in view of U.S. Patent No. 5,593,409 to Michelson. Additionally, claims 1, 2, 5-15, 17, 18, 20, 35-37, 52, 54, 56 and 59-75 were rejected as being unpatentable over U.S. Patent No. 5,645,598 to Brosnahan, III.

Claim Amendments

As an initial matter, the Applicant has cancelled independent claims 12, 60, 65, 70 and 71 and dependent claims 5, 11, 35-37, 69 and 72-74 without prejudice for possible submission and consideration in a continuing application. Accordingly, the subject application now includes pending independent claims 1, 13 and 52 and various claims depending therefrom.

Independent claims 1 and 13 have each been amended to recite, among other elements and features, a generally cylindrical body "having a length and an outer circumferential surface defining an outer circumference", "a side wall discontinuity extending along at least about 50% of the length of said body . . .for nesting with an adjacent spacer" and with "side wall discontinuity defining a side wall opening to said interior chamber" which is "sized to extend over at least about 20% of the outer circumference of said body and along at least about 50% of the length of said body to provide said side wall opening with a size sufficient for loading osteogenic material into said interior chamber", and "said side wall defining a plurality of secondary bone ingrowth openings extending through said outer circumferential surface and into

said interior chamber to facilitate bone ingrowth into said interior chamber, said plurality of secondary bone ingrowth openings sized smaller than said side wall opening".

Independent claim 52 has also been amended to recite, among other elements and features, a generally cylindrical body "having a length and an outer circumferential surface defining an outer circumference" and "said side wall defining a main side wall opening to said interior chamber and configured to extend over at least about 20% of the outer circumference of said body and along at least about 50% of the length of said body to provide said main side wall opening with a size sufficient for loading osteogenic material into said interior chamber" with "said side wall further defining a plurality of secondary side wall openings extending through said outer circumferential surface and communicating with said interior chamber to facilitate bone ingrowth into said interior chamber" with "said plurality of secondary side wall openings sized smaller than said main side wall opening", and "said end walls each having an external profile comprising a first portion defining an arc of a circle . . . extending from 180° to 324° around the circle . . . [and] a second portion defining a concave surface with said main side wall opening extending through said concave surface and into communication with said interior chamber".

Support for the recitation regarding the spacer body "having a length and an outer circumferential surface and defining an outer circumference" is found throughout the specification where repeated references are made to the length, circumference and outer surface of the spacer. Support for the recitation regarding the side wall discontinuity "extending along at least about 50% of the length of said body" is found, for example, at page 10, lines 18-22, and in previously presented claim 11 which has been cancelled without prejudice. Support for the recitation that the side wall opening is sized to "extend over at least about 20% of the outer circumference of said body and along at least about 50% of the length of said body to provide said side wall opening with a size sufficient for loading osteogenic material into said interior chamber" is found, for example, at page 4, lines 14-16 and lines 21-25, at page 12, lines 7-10. Finally, support for the recitation regarding the secondary bone ingrowth openings "extending through said outer circumferential surface and into said interior chamber to facilitate bone ingrowth into said interior chamber" and "sized smaller than" the side wall opening is found, for

example, at page 10, lines 26-28, and in previously presented claims 5 and 69 which have been cancelled without prejudice. The Applicant also notes that the recitation regarding the first and second end walls being "fixed and non-removable relative to said elongated body" has been removed from independent claim 1 and has been reintroduced in new dependent claim 83.

With regard to Zdeblick, as asserted on page 3 of the Office Action, the truncated side walls 22 of the implant 10 have been construed as "a side wall discontinuity" extending along a length of the implant body and configured for nesting with an adjacent spacer, and the vascularization openings 24, 25 have been construed as "a side wall opening" defined by the truncated side walls 22. Even assuming arguendo that the characterization of Zdeblick is accepted, independent claims 1, 13 and 52 each recite features that are neither disclosed nor suggested by Zdeblick.

Specifically, even if the vascularization openings 24, 25 were construed to comprise "a side wall opening" defined by a side wall discontinuity extending along at least about 50% of the implant body, neither of the vascularization openings 24, 25 are sized "to extend over at least about 20% of the circumference of said body and along at least about 50% of the length of said body" to provide the side wall opening with "a size sufficient for loading osteogenic material into said interior chamber", as recited in each of independent claims 1, 13 and 52. Indeed, Zdeblick specifically indicates that "the overall length of the device [is] 26 mm" (col. 7, lines 46-47), and "the vascularization opening 24 is generally rectangular in shape having dimensions of 6.0 mm by 7.0 mm [and] the vascularization opening 25 is rectangular with dimensions of 4.0 mm by 5.0 mm." (Col. 7, lines 58-63). Accordingly, neither of the vascularization openings 24, 25 defined by the side wall 22 extend along anywhere near 50% of the overall length of the implant 10. To the contrary, the vascularization opening 24 extends along only about 25% of the length of implant 10 (7.0mm out of 26mm), and the vascularization opening 25 extends along only about 20% of the length of the implant 10 (5.0mm out of 26mm). Furthermore, the heights of the vascularization openings 24, 25 do not "extend over at least 20% of the outer circumference" of the implant, which equates to a circumferential arc of at least about 72 degrees. Instead, the vascularization openings 24, 25 extend over significantly less than 20% of the outer circumference of the implant 10. As a result, the size of the vascularization openings

24, 25 do not satisfy the requirements set forth in independent claims 1, 13 and 52, and are not provided with a size sufficient for loading osteogenic material into the interior of the implant. Moreover, even if the vascularization openings 24, 25 were construed to comprise "a side wall opening" defined by a side wall discontinuity, the implant 10 does not define "a plurality of secondary bone ingrowth openings extending through said outer circumferential surface" which are "sized smaller than" the side wall opening, as recited in each of independent claims 1, 13 and 52. Indeed, the only openings which extend through the outer circumferential surface of the implant 10 are the slotted openings 27. However, the slotted openings 27 are clearly sized significantly larger than the vascularization openings 24, 25, both in length and width.

Additionally, if the slotted openings 27 were somehow construed as "a side wall opening", the slotted openings 27 are not defined by "a side wall discontinuity extending along at least about 50% of the length of said body", as recited in independent claims 1 and 13. To the contrary, the slotted openings 27 extend through the threaded circumferential portions of the implant 10, which extend continuously along the length of the implant without interruption. The slotted openings 27 likewise do not comprise a main side wall opening "extending through said concave surface and into communication with said interior chamber", as recited in independent claim 52. Instead, the slotted openings 27 extend through the convex threaded portions of the implant 10, which clearly do not in any way define a concave surface. Furthermore, the slotted openings 27 do not "extend over at least about 20% of the outer circumference of said elongated body". To the contrary, the slotted openings 27 are relatively narrow, and do extend about at least 20% of the outer circumference of the implant (i.e., along a circumferential arc of at least about 72 degrees). Moreover, even if either of the slotted openings 27 were somehow construed to constitute a "side wall opening" defined by a side wall discontinuity, the implant 10 does not define "a plurality of secondary bone ingrowth openings extending through said outer circumferential surface", as recited in independent claims 1, 13 and 52. Although the implant 10 includes a plurality of vascularization openings 24, 25, such openings do not extend through an outer circumferential surface of the implant, but instead extend from the flat/planar surface defined by the truncated side walls 22.

Furthermore, Zdeblick teaches that "[i]t has been found that these dimensions of the vascularization openings 24, 25 and the slotted openings 27 provide optimum bone ingrowth and vascularization. In addition, these openings are not so large that they compromise the structural integrity of the device or that they permit the bone graft material contained within the hollow interior 15 to be easily expelled during implantation." (Col. 7, line 67 to col. 8, line 6; emphasis added; see also, col. 6, lines 41-46). Accordingly, Zdeblick specifically teaches away from the recited feature of providing a side wall opening "with a size sufficient for loading osteogenic material into said interior chamber", for to do so would correspondingly allow the bone graft material to be "easily expelled during implantation", which is directly contrary to the teachings of Zdeblick. Additionally, Zdeblick teaches away from increasing the size of the vascularization openings 24, 25 and the slotted openings 27, for to do so would "compromise the structural integrity of the device", which is likewise contrary to the teachings of Zdeblick.

With regard to Michelson, although the implant 800 illustrated in Figure 42 appears to define a side wall discontinuity 806 and a number of slotted openings 828, 829 in communication with a hollow interior of the implant, the slotted openings 828, 829 are quite small, and none are sized to extend about at least 20% of the outer circumference of the implant and along at least about 50% of the length of the implant. Notably, although the slots 828 extend about a portion of the outer circumference of the implant, the dimension of the slots 828 along the length of the implant is very narrow, and clearly does not extend along anywhere near 50% of the implant length. Additionally, the slots 829 appear to extend along less than 50% of the implant length, and clearly do not extend about anywhere near 20% of the circumference of the implant (i.e., along a circumferential arc of at least 72 degrees). As a result, none of the slots 828, 829 are provided with "a size sufficient for loading said osteogenic material into said interior chamber", as recited in independent claims 1, 13 and 52. Moreover, even if the slots 828 were construed to comprise "a side wall opening" defined by a side wall discontinuity, the implant 10 does not define "a plurality of secondary bone ingrowth openings extending through said outer circumferential surface" which are "sized smaller than" the side wall opening, as recited in each of independent claims 1, 13 and 52. Indeed, the only openings extending through the outer circumferential surface of the implant 800 are the slots 820. However, the slots 829

clearly are sized significantly larger than the slots 828, both in length and width. The remaining implant embodiments disclosed in Michelson include small openings that clearly would not satisfy the size requirement of the side wall opening recited in independent claims 1, 13 and 52 so as to provide the side wall opening with a size "sufficient for loading said osteogenic material into said interior chamber".

With regard to Brosnahan, although the implant illustrated in Figure 14 appears to define a side wall discontinuity 48b and a slot 40 extending transversely through the implant, the width of the slot 40 is not sized to "extend about at least 20% of the outer circumference of the implant" (i.e., along a circumferential arc of at least 72 degrees), as recited in independent claims 1, 13 and 52. To the contrary, the slot 50 appears to extend along a circumferential arc of about 30 degrees, which equates to about 8% of the outer circumference of the implant. Additionally, even if the slot 40 were somehow construed to constitute "a side wall opening", the slot 40 is not defined by "a side wall discontinuity extending along at least about 50% of the length of said body", as recited in independent claims 1 and 13. To the contrary, the slot 40 extends through the threaded circumferential portions of the implant, which extend continuously along the length of the implant without interruption. The slot 40 likewise does not constitute a main side wall opening "extending through said concave surface and into communication with said interior chamber", as recited in independent claim 52. Instead, the slot 40 extends through the convex threaded portions of the implant, which clearly do not in any way define a concave surface.

Additionally, the Office Action asserts that it would have been obvious to locate the slot within the concave side wall of the implant. (See page 5). The Applicant respectfully disagrees with this assertion for at least the following reasons. The slot 40 is clearly used to promote bone growth through the fusion device between the adjacent vertebrae. (Col. 5, lines 31-45). In order to accomplish this objective, the openings of the slot 40 must be positioned directly adjacent the vertebrae in order for bone through growth to occur through the fusion device. As a result, there would be no motivation to relocate the slot to extend from the concave surface of the implant, for to do so would not position the openings of the slot 40 adjacent the upper and lower vertebrae. Accordingly, there is no suggestion, and indeed there would be no motivation whatsoever, to position the slot 40 so as to extend between the concave side walls 48b, 50b, for to do so would

prevent, or at least the very least significantly hinder, bone growth through the fusion device. Moreover, even if the slot 40 were construed to comprise "a side wall opening", the implant does not define "a plurality of secondary bone ingrowth openings extending through said outer circumferential surface" which are "sized smaller than" the side wall opening, as recited in each of independent claims 1, 13 and 52. Indeed, the only opening extending through the outer circumferential surface of the implant is the slot 40. Therefore, the implant does not define "a plurality of secondary bone ingrowth openings" that are "sized smaller than" the slot 40.

For at least the reasons set forth above, Zdeblick, Michelson and Brosnahan fail to disclose each of the elements and features recited in independent claims 1, 13 and 52, whether considered along or in combination with one another. Additionally, the claimed invention provides advantages that are not realized by the implant disclosed in the cited references. For example, the claimed spacer is provided with a side wall opening having "a size sufficient for loading osteogenic material into said interior chamber". Such size is provided via configuring the side wall opening "to extend over at least about 20% of the outer circumference of said body and along at least about 50% of said length of said body". However, the openings defined by the implants of Zdeblick, Michelson and Brosnahan are substantially smaller than the side wall opening recited in independent claims 1, 13 and 52. As a result, the implants of Zdeblick and Michelson are provided with a large opening extending through the end of the implant to allow for loading of bone growth material into the interior of the implant. The large end opening must be subsequently covered or closed off by an end cap to retain the material within the interior of the implant. However, due to the presence of the large side wall opening in the claimed implant, "its end walls can be optionally substantially closed, fixed and non-removable." (Page 9, lines 8-13).

Additionally, the claimed implant includes a side wall discontinuity to allow for nesting with an adjacent spacer. Also, since the relatively large side wall opening of the claimed implant is defined by the side wall discontinuity, as illustrated in Figure 8, two adjacent spacers can be positioned such that the side wall openings face one another to provide a large, continuous chamber between the implants. Such feature is clearly not permitted with regard to the implants disclosed in Zdeblick, Michelson and Brosnahan. Moreover, in addition to being provided with

a large side wall opening for loading osteogenic material into the interior chamber, the claimed implant is also provided with a plurality of secondary bone ingrowth openings extending through the outer circumferential surface to facilitate bone ingrowth into the interior chamber. These secondary bone ingrowth openings are "sized smaller than said side wall opening" to allow for bone ingrowth into the implant, yet are sized small enough to retain/maintain osteogenic material within the interior chamber. One again, the implants disclosed in Zdeblick, Michelson and Brosnahan do not provide the unique combination of features recited in independent claims 1, 13 and 52.

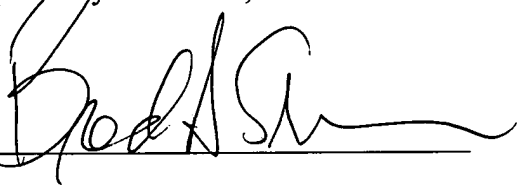
For at least the reasons set forth above, the Applicant submits that claims 1, 13 and 52 are patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1, 13 and 52 and allowance of the same. Claims 2, 6-10, 14, 15, 17, 18, 20, 54, 56, 59, 61-64, 66-68 and 75 depend either directly or indirectly from independent claims 1, 13 and 52, and are submitted to be patentable for at least the reasons supporting the patentability of their respective independent claims. Additionally, the Applicant notes that dependent claims 9, 10 and 59 have been amended in view of the amendments incorporated into independent base claim 1, and dependent claim 62 has been amended in view of the amendments incorporated into independent base claim 13. Additionally, new dependent claims 83-92 have been added to the subject application, and are submitted to be patentable for at least the reasons supporting the patentability of their respective independent claims. Support for new claims 83, 84 and 91 is found, for example, at page 9, lines 10-13. Support for new claims 85-90 and 92 is found, for example, at page 10, lines 18-22.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 1, 2, 6-10, 13-15, 17, 18, 20, 52, 54, 56, 59, 61-64, 66-68, 75 and 83-92.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

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